

Incomplete Response in Late-Life Depression: Getting to Remission With Buprenorphine

NCT02176291

Statistical Analysis Plan

11/20/17

Statistical analysis plan: For dichotomous outcomes, treatment differences will be evaluated using logistic regression. For continuous outcomes, mixed effects models with site as a fixed effect will be performed to test for trajectory over time. For each such analysis, both main effects for site and the site by treatment interaction term will be examined. Simple log-rank tests and Cox proportional hazard models will be the primary analytic approaches to compare time to remission among groups. A logistical model will be used to analyze remission at the end of the phase. If the number of remissions is small, then exact tests of proportions will be performed. Repeated measures analyses using linear mixed-effects models (LMEs) will be the approach to examine changes for continuous measures. Analyses will be conducted using the intent to treat (ITT) principle. We will examine dropout attributable to adverse events, utilizing data from the randomized portion of the study, with survival analysis (with censoring at time of dropout or removal from the study). This will include dropout due to patient decision as well as due to clinical decision.